K952719

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510(k) Summary of Information Respecting Safety and Effectiveness

A. Submitter:
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B. Device Names:

Proprietary Name:	Biocircuits IOS™ (In-Office System)
Common Name:	Fluorometer for clinical use
Classification Name:	Fluorometer for clinical use

C Legally Marketed Device:
The IOS™ system is substantially equivalent to the Dade Stratus II immunoassay analyzer, (K890908).

D. Device Description:
The IOS™ system consists of the IOS™ instrument, a Buffer Start-up Kit, a Buffer Kit, the IOS™ Quality Control Cartridge (IOSQC), the IOS™ Sample Pipette, and an IOS™ Software Card. The system performs immunoassay tests close to the point of patient care. The system provides rapid, reliable, and accurate results with minimal user involvement. It performs checks of both the instrument and reagent components every time a testis run.

The Biocircuits IOS™ instrument reads the test information - the analyte that is being run, its calibration coefficients, the lot number and expiration ate from the bar code on the 10S Test Cartridge and then asks the user to add a patient sample. When appropriate, the instrument adds buffer solution to the test cartridge to dilute sample, to rehydrate the dried reagents and to wash out excess sample and reagents.

The easy -to-read multi-line liquid crystal display (LCD) guides the user through each step of the Biocircuits IOS™ operation. The user enters instructions and data via the keypad.

The Biocircuits IOS™ instrument is configured with:
- a syringe pump for dispensing buffer
- a bar cede reader
- optics that read the fluorescent signal
- a waste pump for clearing excess fluid from the test cartridge
- a magnet attached to a motor for spinning the impellers in the cartridge
- a microprocessor that calculates analyte concentration from the fluorescence readings
- a buffer compartment that holds the buffer and waste bottles
- a software card containing the latest version of the software that runs the Biocircuits IOS™

E. Intended Use:
The IOS™ system is intended for use with specific IOS™ test cartridges in clinical laboratories, physicians' office laboratories, and other alternate sites to perform immunoassay testing close to the point of patient care.

F. Comparison] with the Predicate Device:
Table 1 summarizes the comparative features of both the IOS™ and the Stratus II instruments.

G. Performance Data:

Nonclinical testing performed at the manufacturer's laboratories gave the following results:

Accuracy: A comparison of methods obtained by testing 126 patient samples in the manufacturer's laboratories using the 10S T4/TU cartridges and a commercially available fluorescent enzyme immunoassay gave the following results, in the form y = b +mx, with "r" being the correlation coefficient. The samples tested ranged from 1.8 ug/dL to 24.6 ug/dL T4.

T4: y =0.229+ 0.943x, r = 0.937
TU: y = 7.120+ 0.748x, r = 0.703
FTI: y = -0.037+ 0.959x, r = 0.932

Precision: The following results were obtained from a laboratory study performed at the manufacture for within-day, between-day, and total imprecision:

T4 Control Level	1	2	3
Mean (ug/dL)	8.1	12.9	4,65
SD, overall (ug/dL)	0.72	1.14	0.56
% CV, within-day (n=10)	8.5%	8.8%	14.4%
% CV, between-day (n=40)	5.0%	4.4%	6.9%
% CV, total	8.9%	8.8%	12.1%

T-Uptake Control Level	1	2	3
Mean (% uptake)	32.4	39.7	22.82
SD, overall (% uptake)	1.04	0.93	1.78
% CV, within-day (n=10)	2.9%	2.4%	3.8%
% CV, between-day (n=40)	2.0%	1.1%	5.9%
% CV, total	3.2%	2.3%	7.8%

Clinical testing performed at a typical physician's office laboratory gave the following results:

Accuracy: A comparison of methods using a total of 43 patient samples was performed using IOS™ T4/TU cartridges; the samples were split and sent to the manufacturer's laboratory for retesting on both the IOS™ and on the predicate device. These studies gave the following results, in the form y = b + rnx, with "r" being the correlation coefficient. The samples tested ranged from 1.8 ug/dL to 20.6 ug/dL T4.

T4: y = 1.915+ 0.771x, r = 0.919
TU: y = 3.470+ 0.878x, r = 0.821
FTI: y = 1.814+ 0.775x, r = 0.927

Precision [lie following results were obtained from a study to determine total imprecision:

T4 Control Level	1	2	3
Mean (ug/dL)	7.46	11.75	4.79
SD, overall (ug/dL)	0.75	1.40	1.01
% CV, total	10.1%	1 1.9%	21.2%

T-Uptake Control Level	1	2	3
Mean (% uptake)	32.24	39.63	24.54
SD, overall (% uptake)	1.46	1.06	2.93
% CV, total	4.5%	2.7%	12.0%

It is self-evident from the data and information presented here that the IOS™ system is as safe and as effective, and performs as well as, the predicate device.

Attachment: Table I: Instrument Comparison

TABLE 1
DADE STRATUS II vs. BIOCIRCUITS IOS™
Instrument Comparison

ATTRIBUTE	STRATUS II	IOS
Technology	Front surface fluorometry	Front surface fluorometry
Reagents		
Immobilization Medium	Reaction tab	Plastic cartridge
Dry	Antibody only	Antibody, substrate, other assay-specific reagents as needed
Wet	2 or 3 (depending on assay), loaded by operator at start of each assay	1 (same for all assays), continuously on-board
Delivery	Fully automated	Fully automated
Short Reagent Detect	Yes	Yes
Calibration	By user	At factory
Sample		
Type	Serum or plasma	Serum
Volume	0.2 ml	0.033 ml
Short Sample Detect	Yes	Yes
Optics		
Type	Fluorometer	Fluorometer
Detector	Photomultiplier	Photomultiplier
Light Source	Low pressure mercury lamp	Mercury vapor lamp
Excitation Wavelength	365 nm	365 nm
Emission Wavelength	450 nm	440 nm
Quality Control	Liquid, assay-specific, tested each run	Electronic/instrument, tested each day Liquid, assay-specific, tested once/week
Instrument Calibration	One fluorescent standard on instrument, read prior to each run	Two fluorescent standards on instrument, read prior to each test
Operating environment	22°-320 C	15°-300 c
Data analysis	Microprocessor-controlled Stored standard curves	Microprocessor-controlled Stored standard curves
Data output	LCD display Printed alphanumeric hard copy	LCD display Printed alphanumeric hard copy